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TITLE: GWOT Vascular Injury Study 2 Supplemental Project: Impact of Prophylactic Fasciotomy

PRINCIPAL INVESTIGATOR: Dr. Thomas Walters

CONTRACTING ORGANIZATION: The Geneva Foundation
917 Pacific Ave., Ste. 600
Tacoma, WA 98402

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14. ABSTRACT The majority of battlefield injures involve the extremities and encompasses either isolated or a combination of vascular injury, penetrating trauma, crush, blunt trauma, burns, and fractures. Each of these injuries places the wounded Service members at risk for developing acute extremity compartment syndrome (ACS). Under far forward surgical conditions the policy is to manage these at-risk patients with prophylactic fasciotomies. The objective of this study is to determine the impact of the widespread use of fasciotomies on a mortality, delayed amputation, fasciotomy related morbidities, and fasciotomy wound management.					
15. SUBJECT TERMS Nothing listed					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT Unclassified	18. NUMBER OF PAGES 10	19a. NAME OF RESPONSIBLE PERSON USAMRMC
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INTRODUCTION:

This is a retrospective analysis of a cohort of US service members included in the wartime vascular injury database. Information regarding service members with a lower extremity vascular injury will be used to determine fasciotomy rates, wound management, and iatrogenic complications. The impact of injury and fasciotomy on the service members' return-to-duty and long-term disability will also be examined.

KEYWORDS:

Vascular Injury
Compartment Syndrome
Extremity
Fasciotomy

ACCOMPLISHMENTS:

- IRB protocol continuing approval approved by MRMC IRB (June 2017).
- 89% of 851 of all charts in the database reviewed.
- CY 2002-2012 chart reviews have all been completed.
- Data is currently being analyzed in preparation of publication

What were the major goals of the project?

The overall goal is to determine the impact of the widespread use of fasciotomies on current medical/surgical practices, management guidelines, medical needs, as well as future research direction. The specific aims are:

- Aim 1. Characterization of patients-demographics, injury, fasciotomy.
- Aim 2. Characterize the morbidities associated with fasciotomy.
- Aim 3. Determine the impact of fasciotomy on delayed amputation rate.
- Aim 4. Characterize fasciotomy wound management.

What was accomplished under these goals?

The main focus of this past year two been chart reviews of data collection for patients included in the database. 89% of all charts in the database have been reviewed. Characterization and analysis of data has started, but is still pending.

What opportunities for training and professional development has the project provided?

Nothing to report

How were the results disseminated to communities of interest?

Nothing to report

What do you plan to do during the next reporting period to accomplish the goals?

Complete data analysis and publication.

IMPACT:

Nothing to report

What was the impact on the development of the principal discipline(s) of the project?

Nothing to report

What was the impact on other disciplines?

Nothing to report

What was the impact on other disciplines?

Nothing to report

What was the impact on technology transfer?

Nothing to report

What was the impact on society beyond science and technology?

Nothing to report

CHANGES/PROBLEMS:

A No Cost Extension request has been approved

Changes in approach and reasons for change

Nothing to report

Actual or anticipated problems or delays and actions or plans to resolve them

Nothing to report

Changes that had a significant impact on expenditures

Nothing to report

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Nothing to report

PRODUCTS:

Two posters were presented at the Military Health Services Research Symposium (MHSRS) Orlando, FL. (Aug. 27-30)

Publications, conference papers, and presentations

Journal publications.

Nothing to report

Books or other non-periodical, one-time publications.

Nothing to report

Other publications, conference papers, and presentations.

- Rivera, J. C., D. L. Miller, L. N. Le and T. J. Walters (2017). Fasciotomy and Vascular Injury Outcomes Study (FaVIO): The Impact of Prophylactic Fasciotomy on Hospitalization following Lower Extremity Vascular Injury Military Health Services Research Symposium (MHSRS) Orlando, FL.
- Walters, T. J., D. L. Miller, T. Le and J. C. Rivera (2017). Fasciotomy and Vascular Injury Outcomes Study (FaVIO): Complications Associated with Prophylactic Fasciotomy following Lower Extremity Vascular Injury. Military Health Services Research Symposium (MHSRS) Orlando, FL.

Website(s) or other Internet site(s)

Nothing to report

Technologies or techniques

Nothing to report

Inventions, patent applications, and/or licenses

Nothing to report

Other Products

Nothing to report

PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS:

What individuals have worked on the project?

Name: Thomas Walters

Project Role: PI

Nearest person month worked: 2.4

Contribution to Project: Dr. Walters is a research physiologist and a member of the Extremity Trauma and Regenerative Medicine Task area at the U.S Army Institute of Surgical Research, San Antonio, TX. He directs the muscle trauma research laboratory and has expertise in animal and human research. His research focus is on the treatment and detection of acute compartment syndrome and related issues involving combat related muscle trauma. He is experienced in conducting retrospective studies involving battlefield extremity trauma from the wars in Iraq and Afghanistan. He is the co-chair of Combat Casualty Care Research Program Integrated Product Team tasked with identifying alternatives to fasciotomy. Dr. Walter's provides the necessary scientific leadership, administrative oversight, and support for all aspects of the study, and ensure personnel and departmental resources are properly aligned to achieve the scope of work.

Name: Diane Miller

Project Role: Program Manager

Nearest person month worked: 12

Contribution to Project: Ms. Miller is responsible for the day-to-day operations of the study. She will be responsible for assisting compilation of radiographic images and may assist with chart abstraction. She will also assist with the preparation of all study related correspondence and technical reports, maintain research files and data, procure study supplies and coordinate all procurement requests through The Geneva Foundation, and ensure budgetary adherence.

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

Leslie DuBois and Julie Cutright have left the project since data collection is completed.

What other organizations were involved as partners?

Nothing to report

Organization Name:

Location of Organization:

Partner's contribution to the project (identify one or more)

☐ Financial support;

☐ In-kind support (e.g., partner makes software, computers, equipment, etc., available to project staff);

- ☐ Facilities (e.g., project staff use the partner's facilities for project activities);
- ☐ Collaboration (e.g., partner's staff work with project staff on the project);
- ☐ Personnel exchanges (e.g., project staff and/or partner's staff use each other's facilities, work at each other's site); and
- ☐ Other

SPECIAL REPORTING REQUIREMENTS:

Quad Chart: Updated quad chart is attached.

APPENDICES:

Appendix A: Fasciotomy and Vascular Injury Outcomes Study (FaVIO): The Impact of Prophylactic Fasciotomy on Hospitalization following Lower Extremity Vascular Injury

Appendix B: Fasciotomy and Vascular Injury Outcomes Study (FaVIO): Complications Associated with Fasciotomy following Lower Extremity Vascular Injury

GWOT Vascular Injury Study 2 Supplemental Project: Impact of Prophylactic Fasciotomy

BAA Log Number 13180003

W81XWH-14-2-0165

PI: Thomas J. Walters, Ph.D.

Org: USAISR/The Geneva Foundation

Award Amount: \$791,101

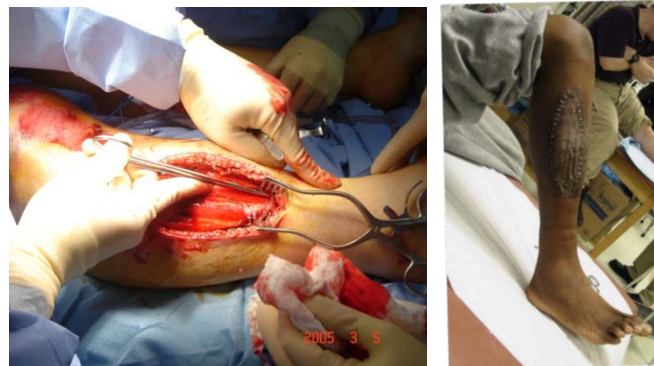


Study/Product Aim(s)

- Specific Aim 1: Identify patients that received fasciotomies and characterize the data relating to demographics, mortality, primary injury, complications, return-to-duty, long-term disabilities.
- Specific Aim 2: Determine the incidence of morbidities associated with fasciotomy; 3) assess the impact of fasciotomy on delayed amputation; and 4) characterize fasciotomy wound management.

Approach

This study will involve a retrospective analysis of a cohort of US Service members included in the GWOTVII database. Information regarding fasciotomy wound management and iatrogenic complications of fasciotomy will be obtained from individual patient records. Information specific for return to duty and long-term disability will be obtained from the Physical Evaluation Board Liaison Office for each branch of service.



(Left) Fasciotomy of the anterior compartment of the lower leg. (Right) The need to close fasciotomy wound with skin graft suggests that muscle swelling was sufficient to induce compartment syndrome. This project will examine the complications and morbidities associated with fasciotomy wounds.

Timeline and Cost

Activities	Year 1	Year 2	Year 3
Obtain IRB/HRPO approval, Hire Staff and FaVIO database development	<div><div></div></div>		
Extract data from GWOTVII database	<div><div></div></div>		
Conduct Chart Reviews		<div><div></div></div>	
Data Analysis and Reporting		<div><div></div></div>	
Estimated Budget (\$791K)	\$339K	\$452K	

Goals/Milestones

CY14 Goal – Protocol/Staffing

- ☒ Write and submit protocol to IRB
- ☒ Hire project manager

CY15 Goals – Data Collection

- ☒ Obtain IRB and HRPO approval
- ☒ Complete staff hiring
- ☒ Extract data
- ☒ Conduct chart reviews

CY16 Goals – Data Collection & Analysis

- ☒ Conduct chart reviews (89% of 851 records reviewed)
- ☒ Analyze data (in progress)
- ☐ Submit results for publication (pending results)

Comments/Challenges/Issues/Concerns

- Currently, staff and PI are working on analysis and publication

Budget Expenditure as of 30 October 2017

Projected Expenditure: \$791,101

Actual Expenditure: \$714,907

Updated: 30 October 2017



Fasciotomy and Vascular Injury Outcomes Study (FaVIO): The Impact of Prophylactic Fasciotomy on Hospitalization following Lower Extremity Vascular Injury

Jessica C. Rivera, MD, Diane L. Miller, RN, Tuan D. Le, MD, DrPH, Thomas J. Walters, PhD

US Army Institute of Surgical Research and San Antonio Military Medical Center Department of Orthopaedic Surgery, JBSA Fort Sam Houston, TX



The opinions or assertions contained herein are the private views of the author and are not to be construed as official or as reflecting the views of the Department of the Army or the Department of Defense.

Introduction

- Severe extremity injuries, including those with vascular injuries, are common combat wounds that account for a majority of the resources expended on the care of combat casualties. (1)
- Fasciotomy rates have increased substantially as educational efforts and guidelines for deployed surgeons have supported the use of prophylactic fasciotomies following vascular intervention. (2,3)
- However, fasciotomies are not benign procedures and cited common local complications include sensory deficits, pain, decreased motion and strength, and limb swelling. (4,5)
- Many of the identified associations between fasciotomy wound problems revolve around delays in wound closure or skin grafting for closure as opposed to delayed primary wound closure by secondary intention. (6)
- Because the fasciotomy wound itself requires treatment that might be protracted due to the need for additional surgery, wound care, and possible wound complications, resource utilization may be adversely affected by the rise in fasciotomy rates.

Objective

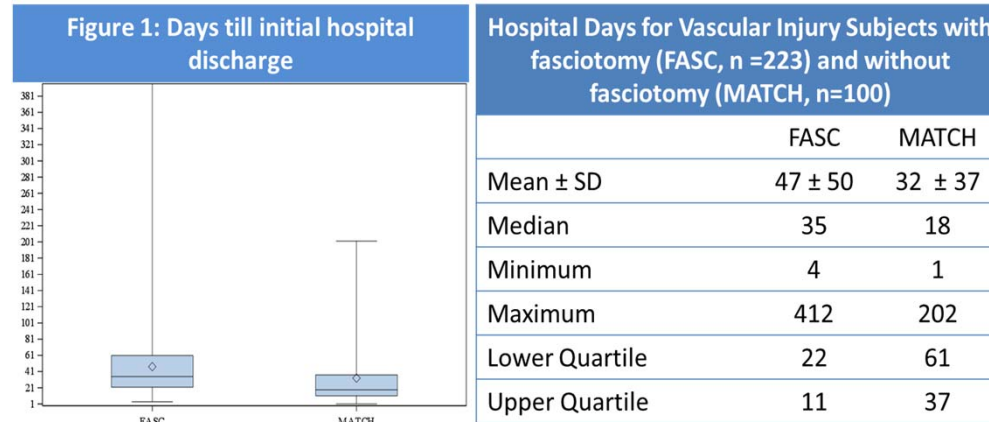
The purpose of this research was to determine if hospitalization utilization was different between Service Members who did and did not undergo fasciotomy relative to their vascular injuries.

Methods

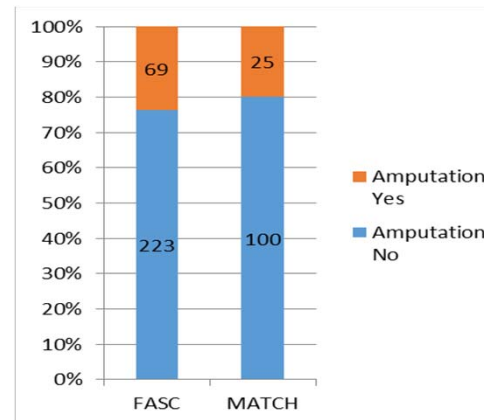
- Retrospective data from the Department of Defense Trauma Registry (DoDTR) and Global War on Terrorism Vascular Injury Initiative (GWOTVII) were used to compare wounded Service Members from 2005-2012 who sustained lower extremity vascular injuries with fasciotomy (n=292) and without fasciotomy (n=125) to the limb with the vascular injury.
- Characteristics of the subjects and injuries were compared including demographics, injury severity score (ISS), mangled extremity severity score (MESS), and associated fractures between the groups.
- Total primary hospital admission days at a level V facility were compared using Wilcoxon Mann-Whitney test.
- Frequency of delayed amputation, defined as amputation within 14 days from injury, was compared using chi-squared analysis.

Results

- Age, sex, mechanism of injury, theater of operation, ISS, and location of vascular injury were not different between subjects with and without a fasciotomy.
- The median number of hospital days was longer for subjects who did not undergo amputation of their vascular injured limb and who underwent a fasciotomy (35 days [range 22-61]) compared to subjects who did not undergo a fasciotomy (18 days [range 11-37]; $p < 0.0001$) (Figure 1)

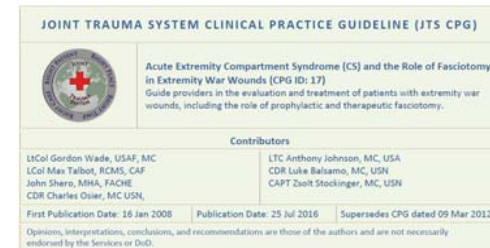


- The rate of fractures was 1.54 times greater in subjects with fasciotomy (57% vs. 37%; $p < 0.0015$).
- The mean numbers of fractures per subject were similar in subjects with and without fasciotomy (1.5 vs 1.6, respectively; $p = 0.6$).
- The MESS score was significantly but not clinically different between subjects with and without a fasciotomy (5.7 ± 1.3 versus 5.3 ± 1.5 , respectively; $p = 0.001$).
- However, delayed amputation rate was not different (23.4% in subjects with fasciotomy versus 20.0% in subjects without; $p = 0.4$). (Figure 2)



Discussion

- Hospital stays are longer in subjects with fasciotomy and may be attributed to the additional care required for the fasciotomy wounds.
- However, additional in-patient utilization may be affected by care of associated injuries such as extremity fracture.
- Amputation was not associated with fasciotomy but likely to be multifactorially driven by factors such as severity of vascular injury, success of vascular intervention, and overall injury burden affecting the reconstructive potential of the limb.
- Deployed surgeons should be referred to the current clinical practice guidelines to understand the role of prophylactic fasciotomy in the deployed environment.



Acknowledgments

We acknowledge the Joint Trauma System and the Department of Defense Trauma Registry for providing data to support this research.

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Statements

This study was conducted under a protocol reviewed and approved by the Brooke Army Medical Center Institutional Review Board in accordance with the approved protocol.



Fasciotomy and Vascular Injury Outcomes Study (FaVIO): Complications Associated with Fasciotomy following Lower Extremity Vascular Injury

Thomas J. Walters, PhD, Diane L. Miller, RN, Tuan D. Le, MD, DrPH, Jessica C. Rivera, MD

US Army Institute of Surgical Research and San Antonio Military Medical Center Department of Orthopaedic Surgery, JBSA Fort Sam Houston, TX



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Introduction

- Fasciotomies are among the most common surgical procedures performed by deployed surgeons.
- Fasciotomy rates have increased substantially as educational efforts and guidelines for deployed surgeons have supported the use of prophylactic fasciotomies following vascular intervention. (1,2)
- Research in the vascular surgery literature indicates that early versus late fasciotomies following vascular trauma were associated with lower rates of infection, a finding that is supportive of prophylactic fasciotomies. (3)
- However, fasciotomies are not benign procedures and cited common local complications include sensory deficits, pain, decreased motion and strength, limb swelling, and concerns about limb cosmesis that can affect quality of life. (4-7)
- While the benefits of a more liberal fasciotomy practice was evident in military populations, the adverse consequences may not be as complication rates associated with prophylactic fasciotomies performed in a deployed environment are not clearly defined.

Objective

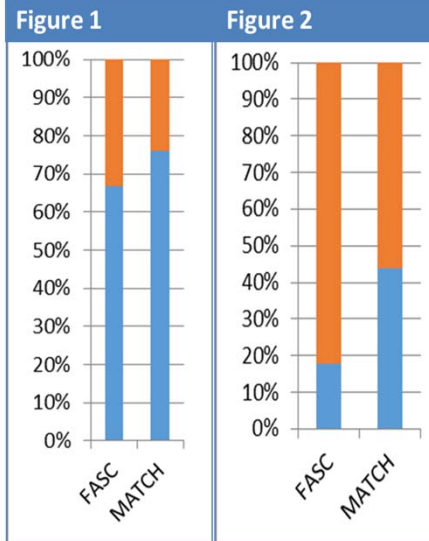
The purpose of this research was to determine vascular and non-vascular related complications were different between Service Members who did and did not undergo fasciotomy relative to their vascular injuries.

Methods

- Retrospective data from the Department of Defense Trauma Registry (DoDTR) and Global War on Terrorism Vascular Injury Initiative (GWOTVII) were used to compare wounded Service Members from 2005-2012 who sustained lower extremity vascular injuries with fasciotomy (n=223) and without fasciotomy (n=100) to the limb with the vascular injury.
- Only those casualties who did not have amputation of the affected limb were included.
- Frequencies of complications were compared between subjects with and without fasciotomy using chi-squared testing.
- Vascular and nerve related complications, non-vascular complications including systemic complications (e.g., rhabdomyolysis, renal failure), non-vascular complication isolated to the limb, and infections of the affected limb were included in the analysis.

Results

- Age, sex, mechanism of injury, theater of operation, injury severity score, and location of vascular injury were not different between subjects with and without a fasciotomy.
- The overall rate of vascular complications was 1.57 times greater in subjects with fasciotomy (OR 1.57 [95%CI: 0.92, 2.69]; p=0.06). (Figure 1)
- Non-vascular complications including systemic complications were higher in subjects with fasciotomy (OR 3.59 [95%CI: 2.13, 6.06]; p=0.003) as were non-vascular complications related directly to the extremity (OR 3.86 [95%CI: 2.25, 6.63]; p<0.0001). (Figure 2)



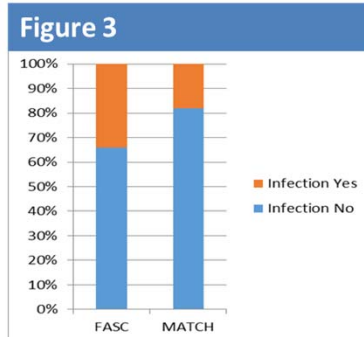
Complications Following Fasciotomy (FASC, n= 223) versus Matched limbs (MATCH, n=100)

	FASC	MATCH
Vascular Complications[‡]		
0	149	76
1-3	71	24
>3	3	0
Non-Vascular Complications*		
0	40	44
1-3	160	53
>3	23	3

[‡]p=0.06; *p<0.0001

Orange YES, complication present Blue NO, complication absent

- The likelihood of infection of affected limb was 2.4 times higher in subjects with fasciotomy versus those without (33.8 vs. 24.5%; p=0.003). (Figure 3)
- Nerve related complications occurred at a 1.34 times greater rate in subjects with fasciotomy (59% vs. 45%; p<0.02).



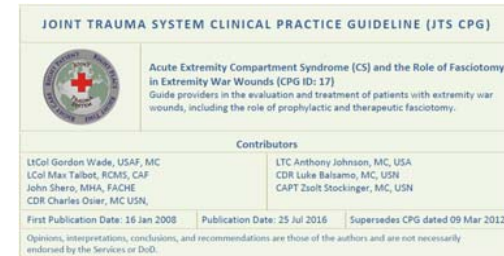
Infections Following Fasciotomy (FASC, n= 223) versus Matched limbs (MATCH, n=100)

	FASC	MATCH
Infection*	76	18
No Infection	147	82

*p=0.003

Discussion

- Service members with lower extremity vascular injuries that undergo fasciotomy have higher complication rates than those who do not.
- The complications are not related to the vascular injury itself but are likely most heavily affected by infection rates.
- The additional wound burden of the fasciotomy wounds may contribute to the infection risk.
- Deployed surgeons should be referred to the current clinical practice guidelines to understand the role of prophylactic fasciotomy in the deployed environment.



Acknowledgments

We acknowledge the Joint Trauma System and the Department of Defense Trauma Registry for providing data to support this research.

References

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Statements

This study was conducted under a protocol reviewed and approved by the Brooke Army Medical Center Institutional Review Board in accordance with the approved protocol.